MAR 1 9 2001

Nicolet
BIOMEDICAL

Summary of Safety and Effectiveness

K010019

Company Name: Nicolet Biomedical Incorporated
5225 Verona Road
Madison, WI 53711

Contact: Glen Hermanson, Manager of Standards and Compliance
Phone: 608 441-2065
Fax: 608 441-2007

Summary Date: December 19, 2000

Trade Name: Sterile Subdermal Needle Electrodes

Common Name: Needle Electrodes

Classification Name: 21 CFR 882.1350, Needle Electrode
21 CFR 890.1385, EMG Needle Electrode

Predicate Device(s):

510(k) Number: K934779
Manufacture: AGRAM Export-Import Company
Trade Name: AGRAM Spyral Electrode
Product Code: 84 GXZ

510(k) Number: K990015
Manufacture: TechnoMed Europe
Trade Name: Various Needle Electrode
Product Code: 89 IKT

1.0 Description of Electrodes

Subdermal needle electrodes are single patient use, disposable, sterile devices. Electrodes are applied in the study of biopotentials such as electroencephalograph (EEG), electromyograph (EMG), nerve conduction and stimulation/response. Electrodes are invasive as they are placed subcutaneously or in contact with nerve or muscle tissue.

The electrodes consist of a formed stainless steel needle with a lead wire attached. The lead wires terminate in a safety connector that cannot be connected to an AC power outlet.

The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and stimulation/response equipment. The electrodes are used under the supervision of a physician.

2.0 Intended Use of Electrodes

Sterile subdermal needle electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals.

3.0 Technological Characteristics

The electrodes consist of a formed stainless steel needle with a lead wire attached. The lead wires terminate in a safety connector that cannot be connected to an AC power outlet. The materials are the same as used in the predicate devices.

4.0 Conclusions

The characteristics of the sterile subdermal needle electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nicolet Biomedical, Inc.
c/o Mr. Gary Syring
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K010019
Trade Name: Sterile Subdermal Needle Electrodes
Regulatory Class: II
Product Code: GXZ, IKT
Dated: December 27, 2000
Received: January 02, 2001

Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if ~~known~~): K010019

Device Name: Sterile Subdermal Needle Electrodes

Indications For Use:

Sterile subdermal needle electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K010019

Prescription Use ✓
(Per 21 CFR 801.109)